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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,476	10/05/2006	Masao Sudoh	Q94153	2354

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EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
08/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,476	SUDOH ET AL.	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-12,14 and 15* is/are pending in the application.

4a) Of the above claim(s) *14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is office action is in response to applicant's request for continued examination filed on June 22, 2009.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 21, 2009 has been entered.

Status of Claims

Amendment of claims 1, 3, 5-6 and 9, and cancellation of claims 2, 4 and 13 is acknowledged

Claims 1, 3, 5-12 and 14-15 are currently pending and are the subject of this office action.

Claims 14-15 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 18, 2007.

Claims 1, 3, and 5-12 are presently under examination.

Priority

The present application is a 371 of PCT/JP04/14896 filed on 10/01/2004, and claims priority to foreign application: JAPAN 2003-345125 filed on 10/03/2003.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "which further comprises one or more selected from" without specifying what is being selected (i.e. a substance or a compound or an excipient, etc)..

Claim Rejections - 35 USC § 103 (Maintained Rejection)

Claims 1, 3, and 5-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Toda et. al. (US 6,608,221) in view of Black (US 6,043,223, cited in prior office action) or Sakanaka (US 2003/0104079, cited in prior office action).

Claim 1, 5-6, and 10-11 recite an infusion preparation comprising about 0.01 mg to about 20 mg of (2R)-2-peopylocatanoic acid or salt thereof per mL and about 1 to 5 equivalents of a basic metal ion based on 1 equivalent of (2R)-2-propylocatnoic acid or salt thereof, wherein said infusion preparation comprises at least one selected from metal salt of phosphoric acid, a metal salt of carbonic acid, a metal salt of sulfurous acid, a metal salt of organic sulfonic acid and a metal salt of organic C2-6 carboxylic acid, and optionally further comprises a metal hydroxide as a source of the basic metal ion. Claim 7 further limits claim 1, wherein the infusion has a pH of about 5.0 to 9.0.

For claim 1, Toda teaches a composition comprising (2R)-2-propylocatnoic acid (see title for example). Toda et. al. do not describe an infusion comprising (2R)-2-propyloctanoic acid. However, preparation of infusions of known drugs is a very well known procedure in the art. For example Black describes an infusion preparation of bradykinin that is dissolved in aqueous solution containing sodium hydroxide (basic metal ion) and phosphate buffered saline (PBS, pH ~ 6-8) solution (see column 5, lines 47-62). Black further teaches an infusion of bradykinin (10-40 micrograms/mL) and 0.09% phosphate buffered saline (i.e. sodium chloride) solution (see column 5, fourth

paragraph). This solution is equivalent to a ratio of basic metal ion (sodium) to bradykinin of 3 to 4 to 1.

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to prepare an infusion of a known drug like (2R)-2-propyloctanoic acid comprising a metal salt of phosphoric acid, since infusions of known drugs are common practice in the pharmaceutical industry as demonstrated by the references of Black and Sakanaka, thus resulting in the practice of claims 1, 5-7 and 10-11 with a reasonable expectation of success.

Claim 3, further limits claim 1, wherein the infusion, further comprises one or more from (i) electrolytes, (ii) saccharides, (iii) vitamins and (iv) protein aminoacids. For claim 3, Sakanaka further teaches an intravenous infusion where the active compound is dissolved in an aqueous solution containing: sodium chloride (an electrolyte), phosphate buffer, glucose (a saccharide), liposome or fat emulsion (see paragraph [0235] on page 35).

Claims 8-9, further limit claim 1, wherein the amount of (2R)-2-propyloctanoic acid is about 0.1 to about 20 mg per mL. These are standard concentrations for active substances delivered as infusions. See for example Black, column 5, fourth paragraph, were it says: "For intravenous administration, the concentration of bradykinin (active ingredient) is preferably between about 15 micrograms/mL to 50 mg/mL. It's within the capability of the ordinary artisan to determine these amounts for a particular patient and

adjust dosage amounts based on the observed clinical effectiveness, thus resulting in the practice of claims 8-9 with a reasonable expectation of success.

Response to Applicant's Arguments

The reasons for this rejection have been provided in the previous office action dated January 22, 2009, the text of which is incorporated by reference herein.

The following is in response to Applicant's Arguments, filed on May 21, 2009, which are related to the above rejection.

Applicant's arguments have been fully considered but are not persuasive. Some arguments were already answered in the above rejection, and other arguments are being answered below.

Applicant argues that the infusion of the present invention cannot be prepared easily even if the teachings of Black or Sakanaka are combined with (2R)-2-propylocatanoic acid disclosed by Toda. Applicant then goes into the details of each reference and why it wouldn't be obvious to reach at the present invention, based on those details.

Examiner's response: Making infusions of known compounds does not require any inventive steps. It is an extremely well known technique in the pharmaceutical/medicinal art. The two references: Black and Sanaka are two of the thousands that the Examiner could have provided to make this point. Most of them include physiological saline distilled water, phosphate buffer, glucose solution, electrolytes, etc. Even though the structures disclosed by Black (Bradykinin, a peptide) and Sakanaka (Dihydroginsenoside, a steroid with sugar moieties covalently attached) are structurally different from the instant claimed structure (2-propylocatnoic acid, an aliphatic acid), the point made by the references of Black and Sakanaka is that infusions are universally known and have been used extensively with an enormous variety of compounds such as determining the exact components and the quantity of each element of an infusion would be obvious to the skilled in the art for a particular pharmaceutical agent. To further clarify this concept, Examiner refers to the following references: Nema et. al. (PDA Journal of Pharmaceutical Science and Technology (1977) 51:166-171), Akers (Journal of Pharmaceutical Sciences (2002) 91:2283-2300) and Powell et. al. (PDA Journal of Pharmaceutical Science and Technology (1998) 52:238-311) which are cited as evidentiary purposes and not as part of the rejection itself. These three references list common excipients and the range used for parenteral (iv and infusion) formulations. These references clearly indicate that the art of making infusions is very well known. Unless Applicant can prove that the specific infusion claimed has unexpected properties that could not be anticipated by the teachings of the prior art, the Examiner maintains the position that it would have been obvious to the

skilled in the art to make an infusion of a known drug ((2R)-2-propylocatanoic acid), since making infusions are standard practice in the pharmaceutical industry as demonstrated by the above references

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
August 20, 2009.

/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642